IN THE UNITED STATE DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
NORTHERN DIVISION

UNITED STATES OF AMERICA ex rel. DOUGLAS ESTEY; STATE OF TENNESSEE ex rel. DOUGLAS ESTEY; and STATE OF VIRGINIA ex rel. DOUGLAS ESTEY,	)	
Plaintiffs,	)	
v	)	**DOCKET NO. _____**
TENNESSEE ORTHOPAEDIC CLINICS, P.C.; APPALACHIAN ORTHOPAEDIC ASSOCIATES, P.C.; and APPALACHIAN ORTHOPAEDIC PARTNERS, LLC,	)	**FILED UNDER SEAL**
Defendants.	)	**Jury Trial Demanded**

COMPLAINT

The United States, State of Tennessee, and State of Virginia, by and through Relator Douglas Estey, bring this action under the False Claims Act, Tennessee Medicaid False Claims Act, and Virginia Fraud Against Taxpayers Act, and file this Complaint and allege as follows:

INTRODUCTION

1. This is an action for damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended, against the above Defendants for money damages and civil penalties arising from the presentation by Defendants of false and fraudulent claims to a federal agency for payment of medical devices provided to persons insured by Medicare, Medicaid, and TRICARE.

2. Additionally, this is an action for damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181, *et seq.* against the above Defendants

for money damages and civil penalties arising from the presentation of false and fraudulent claims by Defendants to the State of Tennessee for payment of medical devices provided to persons insured by TennCare, the State of Tennessee's Medicaid program.

3. Additionally, this is an action for damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code. Ann. § 8.01-216.1 *et seq.*, against Defendants Appalachian Orthopaedic Associates, P.C., and Appalachian Orthopaedic Partners, LLC, for money damages and civil penalties arising from the presentation of false and fraudulent claims by the aforementioned Defendants to the State of Virginia for payment of medical devices provided to persons insured by the State of Virginia's Medicaid program.

JURISDICTION AND VENUE

4. Jurisdiction is founded upon the False Claims Act, 31 U.S.C. §§ 3730 and 28 U.S.C. §§ 1331, 1345 and 31 U.S.C. § 3732 which provides that any claim under § 3730 may be brought in any judicial district in which the defendants reside, transact business or in which any act prescribed by § 3729 occurred.

5. Venue in the Eastern District of Tennessee is appropriate under 31 U.S.C. § 3732(a), 28 U.S.C. §§ 1391(b), and 1391(c) as Defendants conduct business within this district.

PARTIES

6. Relator Douglas Estey is a citizen of the United States of America and a resident of the State of Tennessee. At all times relevant to the allegations complained of within this Complaint, Mr. Estey was working as a Physician Assistant for Dr. Steve Smith and Covenant Medical Management. As a result of his contact with former and current patients of the Defendants, as well as authorized distributors of Genzyme, he became aware of the improper practices complained of herein.

7. Defendant Tennessee Orthopaedic Clinics, P.C. ("TOC") is an orthopedic health services provider providing care at nine total offices throughout east Tennessee, located in the cities of Knoxville, Oak Ridge, Lenoir City, and Seymour. TOC's central business office is located 308 North Peters Road, Suite 225, Knoxville, Tennessee 37922.

8. Defendants Appalachian Orthopaedic Associates, P.C., and Appalachian Orthopaedic Partners, LLC, jointly do business as Appalachian Orthopaedic Associates ("AOA"), the largest and most comprehensive provider of orthopaedic services in Northeast Tennessee and Southwest Virginia, with offices in Kingsport, Johnson City, and Bristol, Tennessee. AOA's corporate business office is located at 4105 Fort Henry Drive, Suite 300, Kingsport, Tennessee 37663.

9. Although AOA does not have any offices located in Virginia, its office in Bristol, Tennessee is located almost directly on top of the Tennessee-Virginia state line, and Appalachian Orthopaedic Associates, P.C., is registered as a foreign corporation in Virginia. As such, it provides services to a number of Virginia residents.

FEDERAL HEALTH PROGRAMS

10. Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.*, establishes the Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program. The Secretary of the United States Department of Health and Human Services ("HHS") administers the Medicare Program through the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS.

11. The Medicare program consists of several parts. Medicare Part A provides basic insurance for the costs of hospitalization and post hospitalization care. 42 U.S.C. § 1395c 1395i 2 (1992). Medicare Part B is a federally subsidized, voluntary insurance program that covers

certain non-hospital medical services and products including the treatments at issue in this complaint. 42 U.S.C. § 1395(k), 1395(i), 1395(s). Reimbursement for Medicare claims is made by the United States through CMS. CMS, in turn, contracts with private insurance carriers to administer and pay Medicare Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395(u). In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b) (1994).

12. Medicaid is a joint federal/state program that provides care for indigent and disabled people. Although the Medicaid program is administered by the states, it is funded in a significant part by the federal government. TennCare is the name of the State of Tennessee's Medicaid program.

13. TRICARE, f/k/a CHAMPUS (The Civilian Health and Medical Program of the Uniformed Services), is a government-funded program that provides medical benefits to retired members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members, as well as reservists who were ordered to active duty for thirty (30) days or longer. The program is administered by the Department of Defense and funded by the federal government. Both TRICARE and its former iteration as CHAMPUS shall collectively be referred to herein as TRICARE.

14. At all times relevant to this Complaint, TOC was a participating Medicare, TennCare, and TRICARE provider. TOC submitted claims for payment to Medicare, TennCare, and TRICARE for services and supplies.

15. At all times relevant to this Complaint, Medicare, TennCare, and TRICARE constituted a significant source of revenue for TOC.

16. At all times relevant to this Complaint, AOA was a participating Medicare, TennCare, Virginia Medicaid, and TRICARE provider. AOA submitted claims for payment to Medicare, TennCare, Virginia Medicaid, and TRICARE for services and supplies.

17. At all times relevant to this Complaint, Medicare, TennCare, Virginia Medicaid, and TRICARE constituted a significant source of revenue for AOA.

18. Medicare, TRICARE, TennCare, and Virginia Medicaid shall hereinafter be referred to collectively as the "Federal Health Programs."

19. All of the conduct alleged in this Complaint is alleged to have occurred "knowingly" or with reckless disregard, as those terms are defined in the False Claims Act, 31 U.S.C. § 3729 and related case law.

20. Medicare reimbursement for drugs and biologics administered in the physician's office is based on average sales price ("ASP"), which for single-source drugs is defined as the weighted average of sales of the product's NDCs across all channels (e.g., retail, hospital, and clinic). Volume discounts, prompt pay discounts, cash discounts, charge-backs, and rebates are all taken into account in the calculation of a product's ASP. Medicare determines an ASP payment per billing unit of the product's HCPCS code.

21. Viscosupplementation agents are reimbursed using a blended, multiple-source ASP formula. This means that the ASP-based allowable per HCPCS billing code for that product will depend on the respective products' ASP amounts, as well as the number of units of each code sold during the quarter.

22. The Medicare allowable payment for viscosupplementation agents is ASP + 6% and is updated quarterly, based on sales in previous quarters. Medicare reimburses 80% of the

allowed payment amount, and the patient or patient's secondary insurer/supplemental plan is responsible for remaining 20%.

23. Medicare also provides reimbursement for the administration of viscosupplementation agents through the CPT code 20610. Physicians receive 150% of the payment amount for CPT Code 20610. Medicare reimburses 80% of the allowed payment amount, and the patient or patient's secondary insurer/supplemental plan is responsible for remaining 20%.

24. Medicaid payment policies vary by state, but the Medicaid payment policies for viscosupplementation agent administration and associated office visits typically are similar to those under Medicare, with reimbursement structured according to a physician fee schedule.

25. Viscosupplementation agents such as Synvisc, Hyalgen, Supartz, Orthovisc, and Euflexxa are billed to Medicare and Medicaid in this fashion, including under CPT Code 20610, but with different HCPCS codes for reimbursement of that particular product. Hyalgen and Supartz are billed under HCPCS code J7321, Euflexxa is billed under HCPCS code J7323, and Orthovisc is billed under HCPCS code J7324. Synvisc was billed under HCPCS code J7322 through at least February 2009, and was billed under HCPCS code J7325 subsequent to FDA approval of Synvisc-One.

FACTUAL ALLEGATIONS

26. Relator Douglas Estey is a Certified Physician Assistant and has been working in orthopedics for fourteen years. He has been paid since approximately 1999 to speak with medical providers about Synvisc, which has brought him into contact with many people who produce, sell, and use Synvisc and related products. He has served the last twenty-seven years in the Army National Guard, including the last twelve years as a Physician Assistant. He was deployed on

active duty in Saudi Arabia during Operation Desert Storm and in Afghanistan during Operation Enduring Freedom.

27. As part of their standard business practices, Defendants, through their agents, officers and employees, provide medical care to individuals whose treatment is covered under the Federal Health Programs.

28. Each of the Defendants has provided a medical device to patients that they have represented to be "Synvisc."

29. SYNVISC (hylan G-F 20) and Synvisc-One (collectively "Synvisc") are viscosupplementation agents manufactured solely by the drug manufacturing company Genzyme. Synvisc is used by medical providers, including Defendants, for the treatment of osteoarthritis of the knee. It is characterized as an injectable Class III medical device and governed and approved by the Federal Drug Administration ("FDA"). There is no generic viscosupplementation agent that has been approved by the FDA for sale or use in the United States or that is approved for reimbursement by any of the Federal Health Programs.

30. Only FDA-approved Synvisc may legally be provided to patients. If the product is not FDA-approved, it is not legal, and it is not actually a proper viscosupplementation agent or properly reimbursable by the Federal Health Programs.

31. The common allegation as to each Defendant is that each has supplied unknowing patients with a non-FDA approved substance under the guise that it was Synvisc and fraudulently billed the United States government, State of Tennessee, and (as to AOA) State of Virginia for Synvisc. The non-FDA approved substance actually used is not properly reimbursable under the insurance guidelines of the Federal Health Programs.

32. Upon information and belief, each of the Defendants has purchased what is commonly referred to as "re-imported Synvisc." A re-imported drug is one initially shipped out of the United States for some reason, such as past expiration date, for use overseas. In certain instances, such as herein, these drugs are subsequently "re-imported" to the United States from a black market source. The benefit to the re-importation recipient is the ability to obtain the product for a fraction of the price of its FDA-approved, domestically-sold counterpart.

33. Re-imported drugs such as those complained of herein are not subject to FDA controls, regulations, and protections. The FDA has clearly stated that re-imported drugs do not go through the same oversight and packaging requirements as drugs produced for United States consumption. As such, it is not possible to know what is actually being purchased, be it actual "re-imported Synvisc," adulterated Synvisc, some other substance entirely, or even a placebo. These products are subject to tampering, dilution, modification, spoliation, and other changes which can make them harmful to patients. Accordingly, there are strict laws and regulations regarding imported medical devices.

34. For these reasons, it is not proper to refer to the re-imported substance referenced herein as merely "Synvisc," as will be noted throughout this complaint. For the purposes of this Complaint, however, the imported Synvisc-like substance, which may or may not consist of Synvisc, shall hereinafter be referred to as "re-imported Synvisc."

35. The Federal Prescription Drug Marketing Act allows only the manufacturer to import or reimport prescription drugs into the United States, or if the prescription drug is required for emergency care (which Synvisc is not).

36. Importation of drugs with labeling from the country of origin or replacing the non-United States labeling with a photocopy of the FDA approved package insert are unlawful

under the Federal Food, Drug, and Cosmetic Act. *See e.g.*, 21 C.F.R. 801.15(c)(1) (requiring labeling to be in English); 21 C.F.R. 801.109(b) (labels lack federal caution statement for prescription devices); 21 C.F.R. 801.109(d) (labeling lacks required product description, indications for use, contraindications, warning, precautions, and patient disclosure information).

37. Because the party selling the prescription drugs and medical devices is not registered or licensed by the state to distribute drugs or medical devices, the sale and purchase is not legal.

38. Since at least 2006, TOC has illegally purchased a non-FDA approved, Synvisc-like substance from distributors outside of the United States and provided it to patients under the guise that it was Synvisc. The purchase price for this substance was significantly lower than would be available from Genzyme, the official manufacturer and sole legitimate supplier of Synvisc.

39. Since at least 2006, TOC has unlawfully submitted false claims to the Federal Health Programs for the use of the re-imported Synvisc, using J-code J7325, a code that is uniquely reserved for FDA-approved, brand name Synvisc purchased from Genzyme.

40. Since at least 2006, AOA has illegally purchased a non-FDA approved, Synvisc-like substance from distributors outside of the United States and provided it to patients, under the guise that it was Synvisc. The purchase price for this substance was significantly lower than would be available from Genzyme, the official manufacturer and sole legitimate supplier of Synvisc.

41. Since at least 2006, AOA has unlawfully submitted false claims to the Federal Health Programs for the use of the re-imported Synvisc using J-code J7325, a code that is uniquely reserved for FDA-approved, brand name Synvisc purchased from Genzyme.

42. Since at least 2006, AOA has similarly unlawfully submitted false claims to the Federal Health Programs for the use of other re-imported viscosupplementation agents using their respective HCPCS codes that are uniquely reserved for FDA-approved, brand name viscosupplementation agents purchased from their respective manufacturers.

43. The significance of this practice by each of the Defendants is threefold: a fraud is being perpetrated on the federal Government and the States of Tennessee and Virginia, as they are being billed for and paying for a product not properly reimbursable; the CMS reimbursement rates for legitimate Synvisc are artificially inflated by these practices; and, most importantly, the patients are facing potential grievous physical harm as they are being exposed to a non-regulated injectable device.

A. NOT PROPERLY REIMBURSEABLE

44. Defendants each year fraudulently treat thousands of patients with re-imported viscosupplementation agents that have been imported from foreign distributors.

45. For example, on July 17, 2006, Dr. Michael Casey, who was working for TOC, recommended to patient number 595609 that she proceed with Synvisc injections.

46. TOC treated patient number 595609 with three separate injections of Synvisc into her left knee – on September 29, 2006, October 6, 2006, and October 13, 2006.

47. Patient number 595609 returned to TOC with knee pain, and TOC provided further Synvisc injections – on July 11, 2007, August 17, 2007, August 24, 2007, and on August 31, 2007.

48. At no time did anyone at TOC advise patient number 595609 that any of these injections were not FDA-regulated Synvisc purchased from Genzyme.

49. At no time did anyone at TOC advise patient number 595609 that any of these injections were re-imported Synvisc.

50. Defendants have billed the Federal Health Programs for reimbursement of the re-imported Synvisc as if it were legitimately purchased and regulated Synvisc, when it was in fact re-imported from foreign parties that are not the manufacturer, Genzyme.

51. Since Defendants only use re-imported Synvisc and do not purchase FDA-regulated Synvisc from Genzyme, each and every claim submitted to the Federal Health Programs for reimbursement for using Synvisc was a false claim.

52. Defendant AOA also uses the viscosupplementation agents Hyalgan, Supartz, Orthovisc, and, upon information and belief, Euflexxa.

53. Upon information and belief, AOA does not purchase Hyalgen, Supartz, Orthovisc, or Euflexxa from their respective manufacturers, but rather also purchases re-imported versions of these agents from overseas.

54. Since, upon information and belief, AOA only uses re-imported viscosupplementation agents, each and every claim submitted to the Federal Health Programs for reimbursement for using a viscosupplementation agent was a false claim.

55. In order to acquire Medicare, Medicaid, and TRICARE funds, Defendants TOC and AOA engaged in fraudulent activity by illegally submitting claims to Medicare that they knew were false. Specifically, Defendants TOC and AOA purchased and used re-imported Synvisc on their patients, but submitted claims to the respective Federal Health Care Program for regulated Synvisc purchased from Genzyme, and did so willingly, intentionally and fraudulently.

56. Had the Federal Health Care Programs been aware that TOC and AOA had used re-imported Synvisc, they would not have paid Defendants for their Synvisc claims.

57. Upon information and belief, Defendant AOA also engaged in fraudulent activity by illegally submitting claims to Medicare, TRICARE, TennCare, and Virginia Medicaid that it knew were false, by purchasing and using re-imported Hyalgen, Supartz, Orthovisc, and Euflexxa on its patients, but submitting claims for the respective brand name, regulated viscosupplementation agent purchased directly from the respective manufacturer, and did so willingly, intentionally, and fraudulently.

58. Had the Federal Health Care Programs been aware that AOA had used re-imported viscosupplementation agents, they would not have paid AOA for their claims.

59. Defendants create fraudulent records to support their false claims by noting in the patient files that the patients are being treated with Synvisc, or other brand name agents, and not re-imported viscosupplementation agents.

60. Defendants have engaged in a pattern of behavior that not only defrauds the federal and state governments but also endangers their citizen patients. As stated above, once the protection and regulation of the FDA is removed, there are no safeguards in place to protect the quality of the substance being provided in lieu of FDA-regulated viscosupplementation agents. As a result, patients are being subjected to potentially tainted, adulterated substances in the name of profit.

B. ARTIFICIALLY INFLATED REIMBURSEMENTS

61. Because Defendants submitted false claims to the Federal Health Programs for name brand viscosupplementation agents, rather than for the lower cost, re-imported viscosupplementation agents, the Federal Health Programs reimbursed Defendants for each of these claims at a fixed amount set by CMS for the name brand agents.

62. This amount is calculated by sum of the Average Sale Price and a fixed percentage of profit. The Average Sale Price for a medical device is the average price per unit paid by providers to manufacturers, who are legally required to report all sales to CMS for the calculation of future Average Sale Prices.

63. By purchasing medical devices from foreign suppliers, who do not report their sales to CMS, the extremely low price of the sale is never reported to CMS. The result of the lack of reporting of the low prices obtained by Defendants is that the calculated Average Sale Price is artificially high.

64. As a result of the artificially high Average Sale Prices calculated since Defendants began purchasing re-imported viscosupplementation agents, the Federal Health Programs (including the Medicaid programs for every state) have overpaid **every** provider, including Defendants, for every unit of viscosupplementation agent for which reimbursement was sought, compared to what the reimbursement rate would have been had Defendants reported the prices they actually paid for the re-imported viscosupplementation agent.

65. Because Defendants have been reimbursed based on the Average Sale Price, yet buy the unregulated re-imported viscosupplementation agent at significantly lower prices, Defendants have fraudulently obtained a windfall profit of approximately 94% for each reimbursement they receive.

C. RELATOR'S KNOWLEDGE AND SCIENTER OF DEFENDANTS

66. Relator Douglas Estey has been employed in the medical profession in eastern Tennessee as a Physician Assistant for all times material to the matters complained of herein. He has also been a paid speaker for Genzyme to help educate medical providers about the use of Synvisc. Based on his work with various orthopedic groups, he has a tremendous familiarity with

orthopedic treatment, in particular the use of injectable medical devices such as Synvisc. He is also personally familiar with several Genzyme sales representatives. As stated previously, Genzyme is the sole legal distributor of Synvisc in the United States.

67. Mr. Estey has personal firsthand knowledge of these schemes from reviewing patient records from 2006 through 2008 that indicate that TOC treated patients with what they were told was Synvisc, when TOC did not purchase regulated Synvisc from Genzyme.

68. Relator Estey initially became aware of TOC's illegal importation of purported Synvisc after talking with his uncle, who said he had been treated with what he was told was Synvisc at TOC by Dr. Michael Casey in 2006.

69. Through his work, Relator Estey knows and has conversed with various Genzyme sales representatives, including Mike Gregory and Megan Vesser, and regional manager Adam Barese. Estey has discussed Defendants' purchases of re-imported Synvisc with these representatives on multiple occasions.

70. Relator Estey was consulted by these representatives for his professional advice as to how Genzyme might be able to change Defendants' minds about purchasing unregulated and illegal products and to convince Defendants to purchase products legally from Genzyme. In this way, Relator Estey was acting as an agent directly for Genzyme and obtained original, first-hand knowledge about Defendants' illegal acts.

71. After learning of his uncle's treatment with the re-imported Synvisc, Mr. Estey was personally told by Mike Gregory that TOC had not purchased Synvisc from Genzyme, and that Gregory was perplexed as to how the clinic could be treating patients with Synvisc.

72. Relator also learned from patient number 595609, discussed above, that she was told she was receiving Synvisc injections, when she was in fact receiving injections of re-imported Synvisc.

73. After learning of that patient's treatment with re-imported Synvisc, Mr. Estey again talked with Mike Gregory who confirmed that Genzyme had not sold Synvisc to TOC. Gregory also told Mr. Estey that Genzyme had conducted several meetings with TOC to explain concerns with re-importation of Synvisc and to encourage TOC to purchase Synvisc legally from Genzyme. These meetings were with TOC Drs. Paul Naylor, John Harrison, and John Reynolds as well as several Physician Assistants who work with these doctors and give injections at their direction. Mike Gregory also met with TOC Director of Purchasing William Darrel Bruner and Clinic Director Rhonda Byrd. All of these TOC employees were aware that TOC was illegally using re-imported Synvisc.

74. During one meeting Mike Gregory was asked by a TOC physician to check the lot number of the Synvisc that was in the clinic and ready for use in patients. The lot number indicated that it had been sent from the United States to China, and then re-imported back to the United States.

75. Relator Estey was told by a Genzyme representative that TOC did not even have an account set up with Genzyme with which to purchase Synvisc until April 2011. Thus, all purported Synvisc purchased and used prior to at least April 2011 could not have been purchased from Genzyme and was not FDA approved, making any reimbursement requests for these devices fraudulent.

76. Relator Estey has personal knowledge that AOA treats patients with re-imported Synvisc and bills the Federal Health Programs for the use of Synvisc.

77. Relator Estey verified through Mike Gregory that AOA does not purchase Synvisc directly from Genzyme.

78. Relator Estey verified through Mike Gregory that he and Alisa Green, a special account representative for Genzyme, met with AOA CEO Ken Kisiel and employee Dr. Daniel Klinar in 2008 or 2009. During this meeting, Mr. Kisiel stated that AOA would not be purchasing Synvisc from Genzyme unless it could receive prices for as low as the "Turkish prison camp" from which AOA had been buying re-imported Synvisc.

79. Relator Estey learned that Mike Gregory sponsored a lunch at AOA, during which Mike Gregory examined several units of re-imported Synvisc that AOA had been using. On one unit of re-imported Synvisc, the packaging was different from that used by Genzyme and the name listed was that used by many illegitimate internet companies which sell "generic Synvisc," even though there is no generic version available and Synvisc still has patent protection. After Gregory made this discovery, the AOA physicians present – Drs. Daniel Klinar and Patrick Riggins – became angry with the AOA employees who had shown Gregory the boxes, immediately ended the lunch, and have not allowed Mike Gregory to communicate with AOA since that time.

CONCLUSION

80. As a result of Defendants' false claims, Medicare reimbursed Defendants for medical devices that were purported to be federally-regulated viscosupplementation agents, but were in fact re-imported viscosupplementation agents and thus not entitled to reimbursement.

81. As a result of Defendants' false claims, TennCare reimbursed Defendants for medical devices that were purported to be federally-regulated viscosupplementation agents, but were in fact re-imported viscosupplementation agents and thus not entitled to reimbursement.

82. As a result of Defendants' false claims, TRICARE reimbursed Defendants for medical devices that were purported to be federally-regulated viscosupplementation agents, but were in fact re-imported viscosupplementation agents and thus not entitled to reimbursement.

83. As a result of AOA's false claims, Virginia Medicaid reimbursed Defendants for medical devices that were purported to be federally-regulated viscosupplementation agents, but were in fact re-imported viscosupplementation agents and thus not entitled to reimbursement.

84. As a result of Defendants' false claims and unreported purchases of re-imported viscosupplementation agents, since at least 2006, CMS has overvalued its Average Sale Prices, resulting in over-reimbursement for every claim submitted to a Federal Health Agency by any provider for reimbursement of the cost of viscosupplementation agents.

85. The United States, State of Tennessee, and State of Virginia were damaged as a result of Defendants' submission of false claims and false statements in support of claims.

86. In fact, by driving up the Average Sale Prices for viscosupplementation agents, all states whose Medicaid program has reimbursed claims for viscosupplementation agents since at least 2006 have been damaged as a result of Defendants' submission of false claims and false statements in support of claims.

87. Relator Douglas Estey has direct and independent knowledge of the facts underlying the Complaint, and the facts and allegations underlying this Complaint have not been publically disclosed as defined under the False Claims Act, 31 U.S.C.A. § 3730(e), the Tennessee Medicaid False Claims Act, § 71-5-183(d)(1)(B), or the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.7(A).

COUNT I

Violations of 31 U.S.C. § 3729 – False Claims Act

88. Relators hereby incorporate and reallege herein all other paragraphs as if fully set forth herein.

89. As set forth above, TOC and AOA, by and through their agents, officers and employees, knowingly presented, or caused to be presented to the United States Government numerous false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

90. As set forth above, TOC and AOA, by and through their agents, officers and employees, knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

91. As set forth above, Defendants Appalachian Orthopaedic Associates, P.C., and Appalachian Orthopaedic Partners, LLC, by and through their agents, officers and employees, knowingly conspired to defraud the Government by getting a false or fraudulent claim allowed or paid, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

92. Due to TOC and AOA's conduct, the Government has suffered substantial monetary damages.

93. The United States is entitled to treble damages based upon the amount of damage sustained by the United States as a result of the aforementioned violations of the False Claims Act, 31 U.S.C. §§ 3729-3733, an amount that will be proven at trial.

94. The United States is entitled to a civil penalty of between $5,500 and $11,000 as required by 31 U.S.C. § 3729(a) for each of the fraudulent claims.

95. Relator is also entitled to reasonable attorney's fees and costs, pursuant to 31 U.S.C. § 3730(d)(1).

COUNT II

Violations of Tenn. Code Ann. § 71-5-182 – Tennessee Medicaid False Claims Act

96. Relators hereby incorporate and reallege herein all other paragraphs as if fully set forth herein.

97. As set forth above, TOC and AOA, by and through their agents, officers and employees, presented, or caused to be presented to the State of Tennessee numerous false or fraudulent claims for payment under the Medicaid program knowing such claims to be false or fraudulent, in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A).

98. As set forth above, TOC and AOA, by and through their agents, officers and employees, made, used, or caused to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the state of Tennessee knowing such records or statements are false, in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B).

99. As set forth above, Defendants Appalachian Orthopaedic Associates, P.C., and Appalachian Orthopaedic Partners, LLC, by and through their agents, officers and employees, conspired to defraud the State of Tennessee by getting false or fraudulent claims allowed or paid under the Medicaid program knowing such claims to be false or fraudulent, in violation of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(C).

100. Due to TOC and AOA's conduct, the State of Tennessee has suffered substantial monetary damages.

101. The State of Tennessee is entitled to treble damages based upon the amount of damage sustained by the State of Tennessee as a result of the aforementioned violations of the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 through 71-5-185, an amount that will be proven at trial.

102. The State of Tennessee is entitled to a civil penalty of between $5,000 and $25,000 as required by Tenn. Code Ann. § 71-5-182(a)(1) for each of the fraudulent claims.

103. Relator is also entitled to reasonable attorney's fees and costs, pursuant to Tenn. Code Ann. § 71-5-183(d)(1).

COUNT III

Violations of Va. Code. Ann. § 8.01-216.3 – Virginia Fraud Against Taxpayers Act

104. Relators hereby incorporate and reallege herein all other paragraphs as if fully set forth herein.

105. As set forth above, AOA, by and through its agents, officers and employees, knowingly presented, or caused to be presented to the State of Virginia numerous false or fraudulent claims for payment or approval, in violation of the Virginia Fraud Against Taxpayers Act, Va. Code. Ann. § 8.01-216.3(A)(1).

106. As set forth above, AOA, by and through its agents, officers and employees, knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of the Virginia Fraud Against Taxpayers Act, Va. Code. Ann. § 8.01-216.3(A)(2).

107. As set forth above, Defendants Appalachian Orthopaedic Associates, P.C., and Appalachian Orthopaedic Partners, LLC, by and through their agents, officers and employees,

knowingly conspired to commit a violation of Va. Code. Ann. § 8.01-216.3(A)(1), in violation of the Virginia Fraud Against Taxpayers Act, Va. Code. Ann. § 8.01-216.3(A)(3).

108. Due to AOA's conduct, the State of Virginia has suffered substantial monetary damages.

109. The State of Virginia is entitled to treble damages based upon the amount of damage sustained by the State of Virginia as a result of the aforementioned violations of the Virginia Fraud Against Taxpayers Act, Va. Code. Ann. §§ 8.01-216.1 *et seq.*, an amount that will be proven at trial.

110. The State of Virginia is entitled to a civil penalty of between $5,500 and $11,000 as required by Va. Code. Ann. § 8.01-216.3(A) for each of the fraudulent claims.

111. Relator is also entitled to reasonable attorney's fees and costs, pursuant to Va. Code. Ann. § 8.01-216.7.

PRAYER FOR RELIEF

WHEREFORE, Relator Douglas Estey prays for judgment:

(a) awarding the United States treble damages sustained by it for each of the false claims;

(b) awarding the United States a civil penalty of $11,000 for each of the false claims;

(c) awarding the State of Tennessee treble damages sustained by it for each of the false claims;

(d) awarding the State of Tennessee a civil penalty of $25,000 for each of the false claims;

(e) awarding the State of Virginia treble damages sustained by it for each of the false claims;

(f) awarding the State of Virginia a civil penalty of $11,000 for each of the false claims;

(g) awarding Relator 30% of the proceeds of this action and any alternate remedy or the settlement of any such claim;

(h) awarding Relator his litigation costs and reasonable attorney's fees; and

(i) granting such other relief as the Court may deem just and proper.

Respectfully submitted,

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